



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2015-N-0001]

The Twentieth Food and Drug Administration International Separation Science Society
Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health
Products--WCBP 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Separation Science Society (CASSS), is announcing a meeting entitled "The Twentieth FDA CASSS Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products--WCBP 2016." The purpose of the meeting is to discuss development of biotechnology-derived drug products and analytic methodologies for the development of biotechnology-derived drug products.

DATES: The meeting will be held January 26, 2016, from 8 am, until January 28, 2016, at 5 pm.

ADDRESSES: The meeting will be held at The Mayflower Hotel, 1127 Connecticut Ave. NW, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Linda Mansouria, CASSS, 5900 Hollis St., Suite R3, Emeryville, CA 94608, 510-428-0740, FAX: 510-428-0741, lmansouria@casss.org.

SUPPLEMENTARY INFORMATION:

I. Background:

CASSS is a scientific society providing forums for the dissemination of information and discussions among industry, academic and regulatory professionals founded on the development and applications of separation science. This cosponsored meeting provides state-of-the-art presentations on the technologies used to produce and assess product quality of biotechnology-derived drug products.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of programming and facilities. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at <http://www.casss.org/?WCBP1600>. (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.) The costs of registration for the different categories of attendees are as follows:

| Category | Cost |
|--------------------------|--------------------------------------|
| Industry Representatives | \$1995 (early bird); \$2395 (onsite) |
| Academic | \$795 (early bird); \$895 (onsite) |
| Government | \$795 (early bird); \$895 (onsite) |

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Mayflower Hotel in Washington DC are eligible for a reduced rate of \$295 USD, not including applicable taxes. To receive the reduced rate, contact the Mayflower Hotel (1-877-212-5752) and identify yourself as an attendee of “CASSS--WCBP 2016.” If you need

special accommodations due to a disability, please contact Linda Mansouria (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

III. Transcripts

We expect that transcripts will be available approximately 30 days after the meeting. A transcript will be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: December 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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